UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

ETHICON ENDO-SURGERY, INC.

Plaintiff

v.

HOLOGIC, INC., et al.

Defendants

CASE NO. 1:07cv834

Judge Michael R. Barrett

OPINION AND ORDER

This matter is before the Court pursuant to the motion for summary judgment (Doc. 108) filed by Hologic, Inc. and Suros Surgical Systems, Inc. (collectively, "Hologic"). Plaintiff, Ethicon Endo-Surgery, Inc. ("Ethicon") has opposed the motion (Doc. 132). A reply brief was filed by Hologic (Doc. 152). This matter is now ripe for review.

Background

Ethicon brings this lawsuit against Hologic for patent infringement of four patents, United States patent number 7,226,424 ("the '424 patent"), United States patent number 6,273,862 ("the '862 patent"), United States patent number 6,428,487 ("the '487 patent") and United States patent number 6,752,768 ("the '768 patent") as well as a false advertising claim under the Lanham Act and wilful infringement. Hologic counterclaims for invalidity of patent '487 and '768. Ethicon alleges that Defendants' ATEC ® breast biopsy systems infringe upon several of the claims in the above mentioned patents which relate to Ethicon's Mammotome® breast biopsy systems.

The patents-in-suit enable the vacuum assisted removal of multiple tissue samples with one needle insertion to perform a breast biopsy analysis. The biopsy needle or

"piercer" enters the subject tissue mass and has a port or aperture so that tissue adjacent to the piercer falls into the aperture. Inside the piercer is a cutter that can move back and forth across the aperture or a hollow outer needle rapidly advances over the inner needle to shear tissue within the notched area. Percutaneous biopsy devices can be used with MRI, ultrasounds and stereotactic imaging and may be hand-held for greater mobility and access.

ANALYSIS

Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56©. A court must view the evidence and draw all reasonable inferences in favor of the nonmoving party. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp*., 475 U.S. 574, 587, (1986). The moving party bears the initial burden of showing the absence of a genuine issue of material fact, but then the nonmoving party must come forward with specific facts showing that there is a genuine issue for trial. *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986); *Matsushita*, 475 U.S. at 587. However, the nonmoving party may not rest on the mere allegations in the pleadings. Fed.R.Civ.P. 56(e); *Celotex*, 477 U.S. at 324. Summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56©; *Celotex Corp. v. Catrett, supra* at 322. "By its very terms, this standard provides that the mere existence of *some*

alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.* 477 U.S. 242, 247-48 (1986)(emphasis original). The substantive law of the case determines what facts are material and whether a higher burden of proof is required for a particular element. *Street v. J.C. Bradford & Co.*, 886 F.2d 1472, 1479 (6th Cir. 1989). Ultimately the Court must decide "whether the evidence presents sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Jarrett v. CSX Transp., Inc.*, 2008 U.S. Dist. LEXIS 86256 (N.D. Ohio Sept. 10, 2008) *citing Terry Barr Sales Agency, Inc. v. All-Lock Co.*, 96 F.3d 174, 178 (6th Cir. 1996) (internal quotations omitted).

In ruling on a motion for summary judgment, "[a] district court is not required to speculate on which portion of the record the nonmoving party relies, nor is it obligated to wade through and search the entire record for some specific facts that might support the nonmoving party's claim." *InterRoyal Corp. v. Sponseller*, 889 F.2d 108, 111 (6th Cir. 1989), cert. denied, 494 U.S. 1091 (1990); see also *L.S. Heath & Son, Inc. v. AT&T Information Sys., Inc.,* 9 F.3d 561 (7th Cir. 1993); *Skotak v. Tenneco Resins, Inc.*, 953 F.2d 909, 915 n.7 (5th Cir.), cert. denied, 506 U.S. 832, 121 L. Ed. 2d 59, 113 S. Ct. 98 (1992)("Rule 56 does not impose upon the district court a duty to sift through the record in search of evidence to support a party's opposition to summary judgment ..."). Thus, a court is entitled to rely, in determining whether a genuine issue of material fact exists on a particular issue, only upon those portions of the verified pleadings, depositions, answers to interrogatories and admissions on file, together with any affidavits submitted, specifically

called to its attention by the parties." *Beatty v. UPS,* 267 F. Supp. 2d 823, 829 (D. Ohio 2003).

I. U.S. Patent '862

Hologic argues that it did not infringe on claim 1 of the Patent '862 and moves the court for a finding of non-infringement. Hologic states that Ethicon admits that it cannot prove literal infringement based upon this Court's *Markman* Order. (See Doc. 87.) In addition, Hologic argues that Ethicon cannot proved infringement under the doctrine of equivalents. Although Ethicon admits that there is no literal infringement based upon this Court's prior order (See Doc. 132, FN1), it argues that there is still infringement under the doctrine of equivalents.

"Summary judgment on the issue of infringement is proper when no reasonable jury could find that every limitation recited in a properly construed claim either is or is not found in the accused device either literally or under the doctrine of equivalents." *PC Connector Solutions LLC v. SmartDisk Corp*., 406 F.3d 1359, 1364 (Fed. Cir. 2005). Although infringement under the doctrine of equivalents is a question of fact, "[w]here the evidence is such that no reasonable jury could determine two elements to be equivalent, district courts are obliged to grant partial or complete summary judgment." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc*., 469 F.3d 1005, 1013, 1017 (Fed. Cir. 2006) (*quoting Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39 n.8 (1997)).

The doctrine of equivalents is a doctrine "designed to do equity" and "to relieve an inventor from a semantic strait jacket," *Exergen Corp. v. Wal-Mart Stores, Inc*., 575 F.3d 1312, 1323 (Fed. Cir. 2009) *quoting Perkin-Elmer Corp. v. Westinghouse Elec. Corp*., 822

F.2d 1528, 1532 (Fed. Cir. 1987). "The primary test for equivalency is the 'function-way-result' or 'triple identity' test, whereby the patentee may show an equivalent when the accused product or process performs substantially the same function, in substantially the same way, to achieve substantially the same result, as disclosed in the claim". *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1296-1297 (Fed. Cir. 2009) *citing Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950). However, that is not the only test. "Equivalency may also be proven where the differences between the invention as claimed and the accused product or process are insubstantial." *Id. citing Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 1517-18 (Fed. Cir. 1995) (en banc), rev'd on other grounds, 520 U.S. 17 (1997). The Supreme Court has said:

> [i]n our view, the particular linguistic framework used is less important than whether the test is probative of the essential inquiry: Does the accused product or process contain elements identical or equivalent to each claimed element of the patented invention? Different linguistic frameworks may be more suitable to different cases, depending on their particular facts. A focus on individual elements and a special vigilance against allowing the concept of equivalence to eliminate completely any such elements should reduce considerably the imprecision of whatever language is used. An analysis of the role played by each element in the context of the specific patent claim will thus inform the inquiry as to whether a substitute element matches the function, way, and result of the claimed element, or whether the substitute element plays a role substantially different from the claimed element.

Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. at 40. Pursuant to Federal Circuit precedent, under either test, "a patentee must still provide particularized testimony and linking argument ... between the claimed invention and the accused device or process." *Texas Instruments v. Cypress Semiconductor Corp*., 90 F.3d 1558, 1567 (Fed. Cir. 1996).

Ethicon argues that the accused device has the equivalent of the "cutter axial

transmission" of the '862 patent.[1] The Court has construed "cutter axial transmission" to be a "mechanical gearing assembly that changes motion from the power transmission source to the axial (i.e., forward and back) motion of the cutter." The accused device is driven by compressed air and a piston, not mechanical gears. Compressed air is sent to the piston, which in turn "changes motion from the power transmission source to the axial (i.e., forward and back) motion of the cutter."

A. Function-Way-Result Test

The function-way-result test allows the Court to focus on the *function* served by a particular claim element, the *way* that element serves that function, and the *result* thus obtained by that element. *See Warner-Jenkinson Co. v. Hilton Davis Chem*. Co., 520 U.S. at 39. It is undisputed that the function and result of the accused device is substantially equivalent to the '862 Patent.

It is the opinion of Ethicon's expert, Dr. Arthur G. Erdman ("Erdman") that the piston cylinder of the ATEC® and the axial transmission of the '862 patent are equivalent under this test. (Doc. 138, Erdman Report, ¶117.) It appears to be uncontested that the function-both change motion from the power transmission source to the axial motion of the cutter-and the result-both achieve the axial motion of the cutter-appear to be equivalent. (Id.) However, the way that the claim element serves the function is disputed. Hologic argues that Ethicon has failed to show that the way the ATEC® piston operates is equivalent to that described in the '862 patent as constructed by the Court. The Court agrees.

[1]Claim 1 also includes the "cutter rotational transmission." Although Hologic believes that Ethicon has failed to show that the ATEC® has the equivalent of the that element as well, they have declined to address that issue in its motion for summary judgment.

Erdman's opinion is that the accused device is substantially equivalent to the cutter axial transmission. Specifically, he states "[i]n applying the Court's construction to the accused devices, I have concluded that the ATEC® handpieces contain at least the equivalent of a cutter axial transmission as that element has been construed by the Court." (Doc. 138, Erdman Report, ¶113.) He then goes on to examine the ATEC® device. Erdman sufficiently describes the way that the ATEC® piston works in his report. However, instead of comparing it to the cutter axial transmission device as described in the '862 patent, Erdman compares it to a double acting rodless cylinder which he describes as a pneumatic cylinder that contains a "gearing mechanism" that falls within the literal scope of claim 1 of the '862 patent. (Id., ¶¶113-117.) Ethicon argues that "those of ordinary skill in the art would readily understand [the double acting rodless cylinder] to be an example of a 'cutter axial transmission.'" (Doc. 132, p17). However, contained within the "detailed description of the invention" section of the patent is the following description, "a cutter axial transmission includes the carriage 124, the screw 114, and the screw shaft 120." (See '862 patent, at 10:53-55). The patent does not describe a double acting rodless cylinder and, in fact, the double acting rodless cylinder does not include a carriage, screw or screw shaft. Therefore, the comparison between the ATEC® and the double acting rodless cylinder is insufficient to show that the ATEC® is equivalent to the cutter axial transmission as construed by this Court. Erdman's has not demonstrated support for his generalized conclusion that the accused product is equivalent to the cutter axial transmission under claim 1 of the '862 patent. Had Erdman compared the ATEC® to the device claimed in the '862 patent, summary judgment would likely not be appropriate; however, he did not do so. Ethicon has not provided particularized testimony and linking

argument with respect to this test.

B. Insubstantial Differences Test

To support a finding of infringement here, Ethicon must present particularized testimony and linking argument as to the insubstantiality of the differences to one of ordinary skill in the art between the cutter axial transmission in Claim 1 of the '862 patent and ATEC®. *Amgen Inc. v. F. Hoffmann-La Roche, Ltd.*, 580 F.3d 1340, 1382 (Fed. Cir. 2009). Ethicon argues that Erdman sets forth enough evidence to defeat summary judgment since he opines that "the difference between the piston cylinder in the ATEC® handpiece and the claimed axial transmission (i.e., a mechanical gearing assembly that changes motion from the power transmission source to the axial motion of the cutter) are insubstantial." (Doc. 138, Erdman Report, ¶115.) To support this opinion, Erdman explains that because the purpose of the piston cylinder, i.e., to change motion from the power transmission source into axial movement, is the same as in the corresponding claim element, that the fact that it does so without gears is insubstantial. (Id. at ¶116.) However, other than pointing out that the purpose is the same, Erdman does not explain why the difference between the pistons and compressed air operation of the ATEC® and the mechanical gearing assembly of the '862 patent is insubstantial. Without more, Ethicon can not survive summary judgment.

C. FDA

Ethicon argues that statements made by Joseph Mark on behalf of Hologic in letters written to the FDA support infringement under the doctrine of equivalents. Mark stated, "[t]oday air and electric motors are used interchangeably in device design and implementation by manufacturers of medical devices in the same field of use." (See Doc.

169, Steffes Decl,. Ex. 12 at HOL 0018781). He also said, "use of an air motor verses an electric motor does not change nor does it have any relationship to the intended use, biopsy sample size, quality, etc." (See Doc. 169, Steffes Decl., Ex. 13 at HOL 0027542-43.) This interchangeability is relevant, according to Ethicon, to tell a fact-finder about similarities or differences between the elements. However, it is clear from the letters that they were prepared to supplement the FDA 510K notification. Several district courts have held that it is not proper to consider statements made in a FDA 510K notification. *See Cardiovention, Inc. v. Medtronic, Inc.*, 483 F. Supp. 2d 830, 840 (D. Minn. 2007); *Sunrise Med. HHG, Inc. v. AirSep Corp.*, 95 F. Supp. 2d 348, 405-06 (W.D. Pa. 2000); *Univ. of Fla. Research Foundation, Inc. v. Orthovita, Inc.*, No. 1:96-cv-82-MMP, 1998 U.S. Dist. LEXIS 22648, 1998 WL 34007129 (N.D. Fla. Apr. 20, 1998) (unpublished). See also *Abbott Labs. & Astellas Pharma, Inc. v. Sandoz, Inc.,* 486 F. Supp. 2d 767, 776 (N.D. Ill. 2007)(an admission of bioequivalence is not an admission of infringement under the doctrine of equivalents). In addition, the Federal Circuit has stated that "FDA equivalence is irrelevant to patent law because it involves fundamentally different inquiries." *Johns Hopkins Univ. v. Datascope Corp.*, 543 F.3d 1342, 1349 (Fed. Cir. 2008). Therefore, since the statements made by Mark were done so in further support of the 510K notification, this Court will not consider those statements.

However, even if the Court did give consideration to those statements, they do not prove infringement. Without making the particularized testimony and linking argument necessary to prove infringement as discussed above, these statements alone can not defeat summary judgment.

Therefore, summary judgment is appropriate as to claim 1 of patent '862.

II. U.S. Patent '424

The '424 patent describes a method for using a vacuum-assisted tissue removal device to take tissue samples. (See Doc. 1-1.) Ethicon alleges that the ATEC® infringes claims 1-7, 9, 11-14 of the '424 patent. However, claims 2-7 and 11-14 depend from independent claims 1 and 9, respectively. Claim 1 requires the disposing of tissue in a "tissue sample holder." Claim 9 requires the disposing of tissue in a "tissue storage compartment." These claims set forth various methods for extracting a tissue sample or methods for obtaining a breast biopsy tissue sample. The claims are as follows:

> 1. A method for extracting a tissue sample from a patient, the method comprising the steps of:
>
> > providing an instrument comprising an outer hollow cannula having a closed tissue piercing distal tip and a lateral tissue receiving port disposed proximally of the distal tip, an inner cutting member, and a tissue sample holder disposed proximally of the lateral tissue receiving port; piercing tissue with the distal tip and directing at least a portion of the outer hollow cannula into the patient; drawing tissue into the lateral tissue receiving port of the outer hollow cannula; translating and rotating the inner cutting member for severing a tissue sample from the tissue drawn into the outer hollow cannula with the inner cutting member; disposing the tissue sample in the tissue sample holder without removing the tissue sample from the instrument; and rotating the outer hollow cannula within the patient to obtain a plurality of tissue samples from different angular orientations about a tissue mass without removing the outer hollow cannula from the patient; wherein the severed tissue sample enters the tissue sample holder along a line substantially parallel to a longitudinal axis of the inner cutting member.
>
> 9. A method for obtaining a breast biopsy tissue sample from a patient, the method comprising the steps of:
>
> > providing an instrument comprising an outer hollow cannula

> having a lateral tissue receiving opening; a hollow inner cutting member having a longitudinal axis, a proximal end, and a distal end; and at least one tissue storage compartment removable from the instrument, wherein at least a portion of the tissue storage compartment is aligned with the longitudinal axis of the hollow inner cutting member; receiving breast tissue in the lateral tissue receiving opening of the outer hollow cannula; translating and rotating the inner cutting member to sever a tissue sample from the tissue received in the outer hollow cannula; disposing the tissue sample in the tissue storage compartment; and removing the tissue storage compartment from the instrument without removing the inner cutting member from the instrument.

(Doc. 1-1, 15:53-16:11; 16:39-59.) The Court construed "tissue sample holder" to mean a "container, e.g. receptacle, cartridge, cassette or other tissue sample holder, that is suitable for housing tissue samples during collection and transportation for analysis." (Doc. 87, p8.) Along those same lines, the Court construed "tissue storage compartment" to mean "a container suitable for housing tissue samples during collection and transportation for analysis and is removable from the instrument." (Id. at 12.) It is the position of Ethicon that "the Court described the structural features of a holder and compartment components that are part of the instrument recited in the claims, and did not require that a clinician perform any additional steps in the biopsy procedure with respect to those components." (Doc. 132, p22.) However, it is the position of Hologic that the Court's construction requires that the clinician take the additional step by actually using the holder or compartment for transporting tissue for analysis. (Doc. 113, p 20.) The Court agrees with Ethicon. The construction only requires that the tissue sample holder and tissue storage compartment be <u>suitable</u> for transportation, not that the method actually includes transporting the sample in the holder or compartment for analysis. Therefore, there is no need for the Court to address Hologic's argument that Ethicon has failed to show that

anyone has used the ATEC® tissue filter to transport the samples for analysis.

Next, Ethicon argues that Hologic infringes the '424 patent because they "'provide an instrument' with a tissue sample holder 'suitable for housing tissue samples during... transportation for analysis.'" (Doc. 132, p27.) Hologic states that the ATEC® has a tissue collection filter[2] that is used to collect tissue after it is severed from the body and drawn back through the handpiece by vacuum into collection filter. (Doc. 113, p 19.) However, Hologic states that the ATEC® collection filter is made from a porous material so that liquids may pass through it, thus, making it unsuitable for transporting samples for analysis. (Id.)

Ethicon points out that Hologic's own expert, Mr. Michael Plishka, states that "... Hologic instructs its customers to remove the tissue samples from the tissue sample filter basket or place the tissue sample filter basket into a separate jar containing a fluid such as formalin prior to transporting the tissue samples for analysis..." and that "clinicians who use ATEC® handpieces generally follow Hologic's instructions..." (Doc. 184, Plishka Report, ¶76.) In addition, Ethicon's expert, Dr. Steve Parker, also confirms that the ATEC® tissue filter is suitable for transportation. Parker gives an example similar to the one given by Plishka where he states "when the physician has removed all sonographic evidence of a lesion, the ATEC® tissue sample baske[t] would be placed in a container filled with formalin and transported to the pathologist...." (Doc. 167, Parker Decl., ¶83.) Ethicon also relies on Hologic's "Design History File" to support its argument that the ATEC® infringes

[2]Depending on the expert, the "tissue collection filter" is also called a "tissue sample filter basket," "tissue sample basket" or, simply a "tissue filter." The Court will use the terms interchangeably.

wherein it states that the tissue collection device "collects and retains the morcellated tissue in a convenient and safe package for the pathologist, without the need for additional handling or exposure of the samples by the user." (Doc. 169, Exh. 22.)

Hologic counters that by requiring the tissue filter to be placed into a separate jar this supports their argument that the tissue filter is not suitable for transportation. (See Doc. 184, Plishka Report, ¶72.) To further support this argument, Dr. Michael Nelson stated the following at his deposition:

> Q. So when you open up - you called that the test tube - to try to get at the filter that has the samples, how much blood or liquid is left in the filter?
>
> A. There's a small amount of liquid. It's usually not blood. It's been - it has been - the cores have been bathed, we call it, in the saline. So they're actually quite clean. So there's not any blood, per se, 'cause everything's gone through the filter, gone out into the canister.
>
> Q. So if the samples have been bathed in saline and sucked clean by the time that you open up the test tube and pull the filter out with the samples, there's nothing that would prevent you from taking the filter basket with the samples across the hall or to another room for testing, correct?
>
> ***
>
> A. No, I said when you transfer to the Tefla pad, you always have a few drops - on it. I said if you would take the filter itself, you - you would end up with drops on the floor, and/or if you took it outside of the room, you'd end up with drops on the floor.

(See Doc. 169, Ex. 18, Nelson Depo., 83-85.)

Thus, based upon the conflicting testimony of the experts and the Design History File, there is a genuine issue of material fact making summary judgment on this issue inappropriate.

III. U.S. Patent '487 and '768

Ethicon alleges that Hologic infringes on claims 1 and 10 of the '487 patent and claims 1-2, 7-9 and 12-13 of the '768 patent. The asserted claims describe a surgical biopsy system designed to remove at least one tissue sample from a patient comprising of the following:

(a) a handpiece that includes an elongated, hollow piercer and a cutter;
(b) a power transmission source operatively connected to the cutter;
© a control unit connected to the handpiece;
(d) a display connected to the control unit which includes icons representing various operational modes;
(e) at least one control button operatively connected to the control unit that the operator can used to select an operation mode;
(f) a remote control device operatively connected to and remotely located from the control unit;
(g) a vacuum source that is operably associated with the handpiece and the piercer;
(h) an icon that is associated with the operation of the vacuum source.

See Doc. 1-3, '487 Patent, 15-16 and Doc. 1-2, '768 Patent, 16.

However, Hologic claims that these patents are anticipated under 35 U.S.C. §102(e) by two prior Ethicon patents, U.S. Patent Nos. 6,086,544 ("the '544 patent") and 6,120,462 ("the '462 patent") and, therefore, are invalid. Under 35 U.S.C. §102(e), one is entitled to a patent unless "the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for party...." "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987). Each claim in an issued patent is presumed valid, 35 U.S.C. § 282 (1988), and a party seeking to prove otherwise must establish invalidity by

clear and convincing evidence. *Diversitech Corp. v. Century Steps Inc.*, 850 F.2d 675, 677 (Fed. Cir. 1988). Whether a claim is anticipated by a particular prior art reference is a question of fact. *Rogers Living Trust v. Baxter Int'l*, 1994 U.S. App. LEXIS 28122, 13-14 (Fed. Cir. 1994).

The '487 patent was filed on December 17, 1999 and the '768 patent was filed on June 18, 2002. The inventors on each patent were Dan Dlugos, Jon Buzzard, Mark Burdorff and John Hibner. (See Docs. 1-2 and 1-3.) Both the '544 and '462 patents were filed on March 31, 1999 (Doc. 108-8, Exh. 16 and Doc. 108-9, Exh.17) and, according to Hologic, constitute prior art. The inventors of these two patents were Chris Quatrochi, Randy Raczek, Anthony Nguyen as well as John Hibner and Mark Burdorff. All four patents are assigned to Ethicon. The '487 and '768 patents list the '544 and '462 patents as references cited thereon. (See Doc. 1-3, '487 Patent and Doc. 1-2, '768 Patent).

A. Each and Every Element

As set forth above, each and every element as set forth in the claim must be found, either expressly or inherently described, in a single prior art reference for a claim to be anticipated. *See Verdegaal Bros., Inc.*, 814 F.2d at 631. Hologic argues that it is undisputed that each and every element is found in the prior patents that are claimed in the patents-in-suit. To support this argument, Hologic cites to the deposition of Ethicon's expert, Arthur Erdman, where, according to Hologic, Erdman could not identify a single element of the asserted claims that is not disclosed in the '544 and '462 patents. (See Doc. 113, p28.) Specifically, Erdman said that he is "silent on – on that issue one way or another." When asked if he looked at it, he answered "no." (Doc. 113-1, Exh. 2, Erdman Depo., p151.)

Unfortunately, Ethicon does not address this issue. When the Court reviews the four patents at issue here, it is not clear to the Court that "each and every element" as set forth in the clams is found in the '544 and '462 patents. Specifically, the patents-in-suit claim a "a remote control device operatively connected to and remotely located from the control unit." Comparatively, the '544 and '462 patents do not claim "a remote control device" but simply state, "an alternative way of selecting the operating mode is available to the operator. By a rapid double clicking of a vacuum switch on handpiece the unit is placed in a "scroll" mode of operation." (See Doc. 108-8, Exh. 16, 24:16-20.) Hologic describes this as "remote control buttons." (See Doc. 113, p33.) However, when reviewing the patents-in-suit, it is clear that the "remote control device" claimed is not the same as the "control buttons" on the handpiece. The "control buttons" on the handpiece is claim 3 of the '768 patent and claim 2 of the '487 patent, which are not at issue here. The patents-in-suit indicate to the Court that the "remote control device" is separate and distinct from the handpiece. (See Fig. 3 of Patents '768 and '487.) Therefore, a question of fact exists as to whether or not each and every element as set forth in the claims are found in the '544 and '462 patents.

B. By Another

Even though summary judgment is not appropriate based upon the holding above, the Court will address the arguments of the parties as to whether or not the earlier patents are "by another" due to an uncertainty in the law on the issue.

Hologic argues that the Court must only look to the names listed as inventors on each patent to determine if '544 and '462 patents were filed "by another" before the filing of the '487 and '768 patents.

Ethicon argues that all four patents came out of Project Gateway and that "the '544 and '462 patents are not "by another" but are from the inventors of the '487 and '768 patents' own work under Project Gateway." (Doc. 132, p41.) Project Gateway was Ethicon's multi-year, multi-million dollar effort to develop a new breast biopsy system which began in May 1997. Numerous Ethicon engineers, including the inventors named above, worked to design and develop: "(1) a hand-held surgical biopsy device that could be used without an external support; (2) a control unit that provided power to the hand-held device and included an component for processing information to and from the device; and (3) a user interface that provide a means to select and actuate various operational modes." (Doc. 132, p39.) Ethicon asserts that all four "patents embody work that was performed under the Project Gateway umbrella." (Id.)

35 U.S.C. §102(e) explicitly states that the reference at issue must be "by another." However, this Court finds that the law that defines what constitutes "by another" is muddled. It has been held that the "by another" requirement of § 102(e) may be satisfied where the inventors listed on a prior art patent overlap but are not identical with those listed on a later patent. *See Electronic Planroom, Inc. v. McGraw-Hill Companies, Inc.*, 135 F. Supp. 2d 805, 826 (E.D. Mich. 2001); *In re Land*, 368 F.2d 866, 881, 54 C.C.P.A. 806 (Cust. & Pat.App. 1966) (prior patent application to each inventor singly was prior art to a patent application invented jointly under section 102(e)). However, it has also been held that "even though an application and a patent have been conceived by different inventive entities, if they share one or more persons as joint inventors, the 35 U.S.C. § 102(e) exclusion for a patent granted to 'another' is not necessarily satisfied. *Applied Materials,*

Inc. v. Gemini Research Corp., 835 F.2d 279, 281 (Fed. Cir. 1987). This disparity was evaluated in *Purdue Pharma L.P. v. Boehringer Ingelheim Corp.*, 98 F. Supp. 2d 362 (S.D.N.Y. 2000) where the District Court stated the following:

> On its facts, the *Applied Materials* decision is quite similar to the present case. It is less clear, however, whether the decision alters the general rule, applied in the *Land* decision, that an earlier patent is "by another" within the meaning of § 102(e) if the two inventive entities overlap but are not identical. It is unlikely that the Federal Circuit intended in *Applied Materials* to overrule that proposition, given that the *Applied Materials* decision cites *Land* with approval and makes no mention of reconsidering *Land*.
>
> Rather, *Applied Materials* holds that if a parent patent fully discloses an invention that in fact is the work of an overlapping inventive entity and that is claimed in a continuing application listing that entity, then the presence of that subject matter in the earlier patent indicates that the present invention was already in existence as of the filing date of the parent application. And on that rationale, the invention disclosed in the earlier patent does not constitute prior art capable of anticipating the present invention.

Purdue Pharma L.P., 98 F. Supp. 2d at 380-381. The Federal Circuit could have clearly decided this issue when *Purdue Pharma L.P.* was on appeal, but chose not to without comment. The District Court made the finding above but then went on, in the alternative, to address the additional arguments raised by the defendants as to anticipation. It is this alternative analysis that the Federal Circuit addressed in *Purdue Pharma L.P. v. Boehringer Ingelheim Corp.*, 237 F.3d 1359 (Fed. Cir. 2001) without commenting on the correctness of the district court's analysis of *Applied Materials*.

There is another Federal Circuit decision that may be instructive on this issue, *Riverwood Int'l Corp. v. R. A. Jones & Co.*, 324 F.3d 1346, 1356 (Fed. Cir. 2003). *Riverwood* dealt with three patents-in-suit, the '806, '789 and '361. The '806 was filed on March 24, 1992 and issued on September 7, 1993. Prior to the issuance of the '806

patent, two continuing applications were filed. These continuing applications later became patents ‘789 and ‘361. All three patents have different inventive entities. Kelly Ziegler, Allen Olson and Curt Lovold are the three named inventors on the ‘806 patent. Ziegler is the sole inventor of the ‘789 patent. Ziegler, Jeffrey Lashyro and Gary Vulgamore are the three named inventors of the ‘361 patent. However, Riverwood argues that the contributions of Lashyro and Vulgamore were withdrawn during prosecution leaving Ziegler as the sole inventor of the ‘361 patent. During prosecution of each of the ‘789 and ‘361 patents, Riverwood listed the ‘806 patent as prior art. Defendants argued that the disclosure of the ‘806 patent as prior art constituted an admission or in the alternative was prior art under 35 U.S.C. §120(e). Riverwood argued that only parts of the ‘806 constituted prior art and produced evidence showing that Ziegler was the sole inventor of the relevant parts of the ‘806 patent that provided the foundation for the later patents.

The District Court found that the ‘806 patent was prior art by admission. The Federal Circuit disagreed, stating the following:

> To fully answer the question before us - whether the '806 patent is prior art [under §102(e)] as to the '789 and '361 patents - the district court must look beyond the superficial fact that the references were issued to different inventive entities. What is significant is not merely the differences in the listed inventors, but whether the portions of the reference relied on as prior art, and the subject matter of the claims in question, represent the work of a common inventive entity.

Riverwood Int'l Corp. v. R. A. Jones & Co., 324 F.3d 1346, 1356 (Fed. Cir. 2003) *citing In re DeBaun*, 687 F.2d 459, 462, 214 USPQ 933, 935 (CCPA 1982). The Court held that if Ziegler was the sole inventor of the portions of the ‘806 patent relied upon by the defendant in its obviousness arguments, then the ‘806 patent is not prior art to the ‘789

patent. *Id.* at 1357 The Court further held that if Riverwood sustains its burden of proof that Ziegler is the sole inventor of the '361 patent, then the '806 would not be prior art to that patent either. *Id.* *Riverwood* merely cites to *In re Land* but does not discuss *In re Land* or *Applied Materials* in its decision.

This Court agrees with the reasoning in *Riverwood* and will follow that decision. Although it could be argued that *Riverwood* is distinguishable to the present case because the later patents in *Riverwood* were filed as continuing applications to the first issued patent, this Court does not see that as an issue. The '768 and '487 patents are not continuing applications to the '544 and '462 patents but they do state that they are related to the '544 and '462 patents. (See Doc. 1-2, 1:8-11 and Doc. 1-3, 1:5-8.) Thus, a factual inquiry needs to be done to determine what claims or elements of the '544 and '462 patents were invented by John Hibner and/or Mark Burdorff and which claims or elements of the '487 and '768 patents were also invented by them. Only those claims or elements that are included in all four patents as being invented by Hibner and/or Burdorff would not be prior art. Thus, even if each and every element of the earlier patents are included in the later patents, summary judgment would not be appropriate.

C. Earlier Date of Invention

The parties also address the issue of whether the later patents were, in fact, conceived, prior to the filing of the applications for the earlier patents. Hologic argues that Ethicon has failed to prove this fact. However, based upon the deposition testimony of John Hibner, the 1997[3] and 1998 invention disclosures, and the photographs of the

[3]Hologic argues that this disclosure was not timely produced while Ethicon states that it was. The Court is not going to disregard the 1997 invention disclosure at this

prototypes, the Court finds that an issue of fact exists as to this issue as well.

IV. Lanham Act

Ethicon also seeks damages and injunctive relief under the Lanham Act for false advertising. In order to establish liability under the Lanham Act, the plaintiff must establish that: 1) the defendant has made false or misleading statements of fact concerning his own product or another's; 2) the statement actually deceives or tends to deceive a substantial portion of the intended audience; 3) the statement is material in that it will likely influence a deceived consumers' purchasing decisions; 4) the advertisements were introduced into interstate commerce; 5) there is some causal link between the challenged statements and harm to the plaintiff. *Balance Dynamics Corp. v. Schmitt Indus.*, 204 F.3d 683, 689 (6th Cir. 2000).

Ethicon alleges that it suffered injury as a result of false claims made by Hologic in a white paper authored by Dr. Timothy Goedde in 2004 discussing Ethicon's Mammotome® and Hologic's ATEC® breast biopsy devices as well as an animation video discussing the ATEC® device. Hologic argues that even if Ethicon can satisfy the first four prongs of the test, it can not demonstrate that it suffered any harm. In addition, Hologic argues that there is no ongoing conduct to enjoin since it has stopped using the white paper and animation video.

Ethicon spends a significant amount of time arguing that the claims made by Hologic are literally false. However, for purposes of this motion, Hologic conceded as much. Therefore, the Court will treat the white paper and animation as literally false. Next,

---

time but the parties are permitted to again raise the issue at trial.

Ethicon argues that Hologic's actions were willful, thus, giving rise to a presumption of causation and injury so that a specific showing of harm is not necessary here. A presumption of money damages is permitted where there exists proof of willful deception in cases of comparative advertising where the plaintiff's product was specifically targeted. *Balance Dynamics Corp. v. Schmitt Indus.*, 204 F.3d 683, 694 (6th Cir. 2000) citing *Porous Media Corp. v. Pall Corp.,* 110 F.3d 1329, 1334-36 (8th Cir. 1997). A question of fact exists as to whether or not the actions of Hologic were wilful. Ethicon produces sufficient evidence to raise this question. For example, listing the white paper on its website in an area titled "Published Clinical Papers," comparing the ATEC® to an outdated version of the Mammotome®, and knowing certain assertions needed clinical support could be deemed by a reasonable juror to be wilful. In addition, there is no dispute that the white paper is comparative advertising specifically targeting the Ethicon Mammotome®. Thus, Ethicon is entitled to the presumption of damages as to the white paper. Of course, this is a rebuttable presumption but it is one that will have to be shown at trial since a question of fact exists. Summary judgment is, therefore, not appropriate here.

However, whether or not the animated video targeted Ethicon's Mammotome® is not so clear. It does not specifically mention Ethicon's Mammotome®. Instead, it generally compares the ATEC® to its competitors. Ethicon argues that since the Mammotome® had the largest market share it is specifically targeted in the video. The Court disagrees. Thus, Ethicon is not entitled to the presumption of damages as to the animated video. Without the presumption, Ethicon must establish that it suffered some sort of harm from the use of the animated video. Although the evidence relied on by Ethicon to support its harm appears to be weak (see Doc. 132, p71-72), it is sufficient to survive summary judgment.

As to the request for an injunction, Hologic argues that there is nothing to enjoin since it has stopped using the white paper and the animation video. Ethicon counters that Hologic continues to make the same claims in its current advertising and that it should not have to rely on Hologic's word that it has stopped using the white paper and animation video or that it will not use them again in the future. The Court agrees. *See Innovation Ventures, LLC v. Body Dynamics, Inc.,* No. 08-12711, 2009 WL 877640, at *3-4 (E.D. Mich. March 30, 2009).

Hologic also argues that the Court should sever the equitable claims from the legal claims. However, it is Ethicon's position that it is entitled to a jury trial on the common issues relevant to its claims and that the Court will be bound by the findings of fact of the jury in its determination of the equitable claims citing *Molton Co. v. Eagle-Picher Indus. Inc.,* 55 F.3d 1171, 1174-75 (6th Cir. 1995). (See Doc. 132, p78.) Again, the Court agrees with Ethicon.

V. Willful Infringement

Ethicon alleges that Hologic willfully infringed on the patents-in-suit. To prevail on this claim Ethicon must show that Hologic (1) acted despite an objectively high likelihood that its actions infringed the patents-in-suit; where (2) this objectively high risk was either known or so obvious it should have been known to Hologic. *In re Seagate Technology, LLC*., 497 F.3d 1360, 1371 (Fed. Cir. 2007) (en banc). There appears to be a conflict as to whether or not Hologic must have had actual knowledge of the patents-in-suit in addition to showing the two prongs mentioned above. Hologic argues that Ethicon must prove it had actual knowledge while Ethicon argues that the test is whether Hologic knew or should

have known of the existence of the patents-in-suit. It is clear that pre-*Seagate*, actual knowledge was a required element of willful infringement. *See Imonex Services, Inc. v. W.H. Munzprufer Dietmar Trenner GmbH*, 408 F. 3d 1374, 1377 (Fed. Cir. 2005) (finding of willful infringement "hinges on when the defendants had actual knowledge of [the patentee's] patent rights, and their actions after that time").

Unfortunately, the post-*Seagate* caselaw is not consistent. In *Anascape, Ltd. v. Microsoft Corp.,* 2008 U.S. Dist. LEXIS 111828 (E.D. Tex. Apr. 25, 2008) the district court found that there could be no pre-suit willful infringement because Defendants did not have actual knowledge of the patent prior to being served with the complaint. In addition, the district court in *VNUS Med. Techs., Inc. v. Diomed Holdings, Inc.*, 527 F. Supp. 2d 1072, 1075 (N.D. Cal. 2007), held that actual knowledge was required.[4]

However, there are cases that imply that actual knowledge is not necessary for a successful claim of willful infringement. While discussing willful infringement, the Federal Circuit held, in *Black & Decker, Inc. v. Robert Bosch Tool Corp.,* 260 Fed. Appx. 284, 291 (Fed. Cir. 2008), that although *Seagate* did not affect Bosch's argument that it did not have knowledge of the patents-in-suit, that would not necessarily resolve the issue. The Federal Circuit then rejected the view of willful infringement "that would allow an accused infringer to stay willfully ignorant despite a high likelihood that its actions infringe a valid patent." *i4i L.P. v. Microsoft Corp.*, 2009 U.S. App. LEXIS 28131, 2009 WL 2449024, *9 (Fed. Cir. Dec. 22, 2009). The Court went on to state that "[s]uch a view would allow an infringer to

[4]Although this decision was issued after the decision in *Seagate*, it does not mention *Seagate* and instead relies on *Imonex Services, Inc. v. W.H. Munzprufer Dietmar Trenner GmbH*, 408 F. 3d 1374, 1377 (Fed. Cir. 2005)

escape a finding of willfulness regardless of its conduct at the time the infringement began as long as it presented many defenses after a formal action was filed." *Id.* "Such a view is inconsistent with both Seagate and generally accepted legal principals regarding 'objective' legal analysis." *Id.*

The Court agrees with the rationale in *i4i, L.P.* and finds that in order to prove willful infringement Ethicon must set forth clear and convincing evidence that Hologic knew of the patents-in-suit or should have known about them.

As to patents, '487, '768, and '424, a question of fact exists as to Hologic's actual knowledge.[5] Although Hologic argues that there is no evidence of actual knowledge, Ethicon has produced evidence showing that Hologic monitored relevant third-party patents, which Ethicon's patents certainly would be relevant, and that Hologic's CEO wrote a letter admitting to being "aware of the Ethicon patents." (Doc. 176, Exh. 66.) The patents in existence at the time of the letter were the '862 and the '487, which is the parent of the '768 patent, as well as the '822 patent which is the grandparent of the '424 patent. In addition, whether the two prongs of the *Seagate* test have been is a question of fact. Since there are too many factual issues in dispute on this issue, the Court declines to discuss them in detail. Thus, summary judgment is inappropriate.

VI. Pre-Suit Damages

Hologic argues that Ethicon is not entitled to pre-suit damages for alleged

[5]Since the Court above made a finding of non-infringement as to claim 1 of the '862 patent, it follows that summary judgment is appropriate as to willful infringement of that claim as well.

infringement of patents' 862, '487, and '768 due to Ethicon's failure to comply with the requirements of the marking statute, 35 U.S.C. §287. The statute allows a patentee to mark an article, or, "when from the character of the article, this can not be done," a patentee may mark the packaging of the article with the relevant patent information. *See* 35 U.S.C. §287(a).[6] Hologic argues that Ethicon is required to mark its devices with the relevant patent information since it "can be done." By marking the packaging instead of the devices, according to Hologic, Ethicon violates the marking statute. Ethicon counters that the statute permits the marking of the packaging and that Ethicon marks the packaging for many different reasons.

Hologic relies on *Rutherford v. Trim-Tex, Inc.*, 803 F. Supp. 158 (N.D. Ill. 1992) to support its argument that the marking must take place on the device because it can be done there and, in fact, had been done previously by Ethicon. However, the Court finds that this case more appropriately supports Ethicon's argument. The Supreme Court has held that the primary purpose of 35 U.S.C. § 287 is to provide information to the public concerning "the status of the intellectual property embodied in an article of manufacture or design." *Rutherford v. Trim-Tex, Inc.*, 803 F. Supp. 158, 161 (N.D. Ill. 1992) *quoting Bonito Boats, Inc. v. ThunderCraft Boats, Inc.*, 489 U.S. 141, 168 (1989). "This is consistent with the Court's long-standing focus on the notice effected by the method of marking the patented article rather than on the precise mechanistic compliance with the statute." *Id.* After a lengthy discussion as to the liberal construction given §287(a) and the

[6]As previously set forth above, the Court granted summary judgment for Hologic as to Ethicon's claim of infringement of the '862 patent. Therefore, no pre-suit damages can be permitted as to that patent.

general acceptance by other courts of the concept that marking packaging is acceptable, the Court in *Rutherford* held that the "[a]lternative marking of the package may sufficiently comply with the statute when there is some reasonable consideration presented for not marking the article due to physical constraints or other limitations, or, for reasons that go to the very purpose of the statute, marking the article itself would not provide sufficient notice to the public." *Id.* at 162. In addition to giving due consideration to a variety of factors, including, but not limited to, defacement, custom of the trade, and expense, the *Rutherford* court "notes that above all, a practical common sense approach must be taken when dealing with issues of compliance for the marking provisions of § 287." *Id.* at 163.

However, in support of Hologic's argument, the Court in *Rutherford* does provide a limitation on the "alternative marking" approach. That limitation being "[w]here the patented article has markings or printing on it, other than the appropriate patent marking, then the alternate form of patent marking on the package is not sufficient compliance with the statute." *Id. citing John L. Rie, Inc. v. Shelly Bros., Inc.*, 366 F. Supp. 84, 90-91 (E.D. Pa. 1973) (E.D. Pa. 1973)(§ 287 strictly construed where patented bag closure device had plaintiff's name and address printed on it, thus patent marking on package did not comply with statute); *Creative Pioneer Products Corp. v. K-Mark Corp.*, 5 U.S.P.Q.2d 1841, 1847-48 (S.D. Tex. 1987)(patent marking on the tool's package insufficient to comply with statute where the wire stripper tool had other lettering and calibrations embossed on its handle).

If this Court accepted this limitation Hologic would be entitled to summary judgment on this claim. However, after careful consideration, the Court finds that the best approach is to not create a hard and fast rule like the limitation referenced in *Rutherford* but to

consider the presence of other markings on an article as an additional factor. The reasoning for this holding is that the purpose of the statute is to give notice to the public and in certain situations, like the present case, marking the device with information other than the relevant patent information may be more practical and more informative to the public. For example, Ethicon argues that its capital equipment, which includes a reusable holster attached to a console unit, is only purchased once by the consumer while the probes are purchased multiple times. Thus, the more current patent information can be made available to the public on the packaging of the probes verses the capital equipment which could contain out of date information.

Therefore, based upon this Court's holding, summary judgment is not proper. Again, the disputed facts are numerous, thus, the Court declines to address each separately, other than to say a question of fact exists as to whether or not Ethicon complied with the requirements of the marking statute.

CONCLUSION

Based upon the foregoing, the motion for summary judgment (Doc. 108) is hereby DENIED, in part, and GRANTED, in part. This matter shall proceed to trial consistent with this opinion.

IT IS SO ORDERED.

s/Michael R. Barrett
UNITED STATES DISTRICT JUDGE